

REMARKS

Claims 9 and 19-21 are pending in this application. All other claims have been canceled without prejudice or disclaimer.

Claim 9 is amended for clarity by incorporating language from the explanation from the previous response that the examiner found useful. Support for the amendment can be found throughout the specification, see Example 1, the introduction of the "SEQUENCE INFORMATION," SEQ ID NO:1, and Example 5. Applicants therefore respectfully request withdrawal of the indefiniteness rejection.

The prior art rejection is discussed below.

***The claims are not rendered obvious by the combination
of Smith, Baxter and Varty***

The examiner cited Smith for disclosing CR1 Polypeptides that are derivatized with myristoyl. The Baxter publication was cited by the examiner for disclosing the constituents of SOLTRAN. Varty was cited by the examiner for disclosing the use of SOLTRAN for organ perfusion. Applicants respectfully traverse this rejection.

At the outset, a claim is not patentable if the invention is obvious to one of ordinary skill in the art. *Graham v. John Deere Co.*, 383 U.S. 1 (1966). The *Graham* test is an objective one, and requires consideration of: (1) the scope and content of the prior art, (2) the differences between the prior art and the claims at issue, and (3) the level of skill in the pertinent art. More than one prior art reference can be relied upon for the obviousness inquiry. If all of the claim elements are disclosed within the prior art

references and there is some reason to combine those references in a manner according to the claim, the claim likely will be obvious. That is, if there is only a need for ordinary innovation to progress from the prior art to the claimed subject matter, that claimed subject matter will likely be considered *prima facie* obvious. *KSR International Co. v. Teleflex, Inc.*, 127 S.Ct. 1727 (2007).

However, when claims are directed to chemical entities, the inquiry turns to similarities and differences between the claimed subject matter and those of the prior art. In basing obviousness on the availability of modifications, *KSR v. Teleflex* presupposes that the art gives **reasons** to make a modification. However, where the art is unpredictable, which is the case in the chemical arts, *KSR's* focus on "identifiable, predictable solutions" presents a difficult hurdle for the examiner because an alleged potential solution based upon the prior art is not genuinely predictable. *Eisai Co. v. Dr. Reddy's Laboratories Ltd.*, 87 USPQ2d 1452, 1456-57 (Fed. Cir. 2008)

Here, the examiner has focused on the existence and previous uses of SOLTRAN (Baxter and Varty). However, these references concern the use of SOLTRAN alone as a perfusion solution for storage. Applicants' claimed invention is very different in that flush storage solution (e.g., SOLTRAN) is being used in an **entirely different and non-obvious context**, namely as a delivery vehicle for the soluble derivative to be carried to where it is needed in the organ. Accordingly, a flush storage solution must be such that the activity of the soluble derivative will be maintained and delivered to the sites in the organ where it is needed. Baxter and Varty

provide no suggestion, motivation or expectation of successfully achieving such a result. In other words, the examiner has not been able to identify a reason provided by the prior art references or common knowledge in the field for making the combination.

In fashioning the rejection, the examiner has seemed to focus on the prior existence of certain components recited in the claims. However, the Patent Act specifically permits patents on new and useful processes that include a new use of known compositions or materials. See 35 USC §§ 100(b), 101.

In other words, the combination of the Baxter and Varty references with the Smith reference is nowhere supported by the references or in the common knowledge of the art. Accordingly, the rejection calls to mind the Federal Circuit decision of *In re Rouffet*, 149 F.3d 1350 (Fed. Cir. 1998), where the court explained:

As this court stated, “virtually all [inventions] are combinations of old elements.” *Environmental Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 698, 218 USPQ 865, 870 (Fed. Cir. 1983); see also *Richdel, Inc. v. Sunspool Corp.*, 714 F.2d 1573, 1579-80, 219 USPQ 8, 12 (Fed. Cir. 1983) (“Most, if not all, inventions are combinations and mostly of old elements”). Therefore an examiner may often find every element of a claimed invention in the prior art. If identification of each claimed element in the prior art were sufficient to negate patentability, very few patents would ever issue. Furthermore, rejecting patents solely by finding prior art corollaries for the claimed elements would permit an examiner to use the claimed invention itself as a blueprint to defeat the patentability of the claimed invention. Such an approach would be an “illogical and inappropriate process by which to determine patentability.” *Sensonics, Inc. v. Aerosonic Corp.*, 81 F.3d 1566, 1570, 38 USPQ2d 1551, 1554 (Fed. Cir. 1996).

To prevent the use of hindsight based on the invention to defeat patentability of the invention, this court requires the examiner to show motivation to combine the references that create the case of obviousness. In other words, the examiner must show

select the elements from the cited prior art references for combination in the manner claimed.


In re Rouffet, 149 F.3d 1350, 1357 (Fed. Cir. 1998).

Applicants submit that the rejection does not satisfy the strictures of the *Rouffet* decision. The references are not combinable without proscribed hindsight. For further clarity, applicants have amended the claims to recite that the complement inhibitory activity is retained by the preparation. Applicants request that the rejection be withdrawn.

REQUEST

Applicants submit that claims 9 and 19-21 are in condition for allowance, and respectfully request favorable consideration to that effect. The examiner is invited to contact the undersigned at (202) 434-1610 should there be any questions.

Respectfully submitted,



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Date

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